

§ 172.868

(4) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(5) Olestra shall not be considered as a source of fat or calories for purposes of §§ 101.9 and 101.13 of this chapter.

(f) Consistent with its obligation to monitor the safety of all additives in the food supply, including olestra, the Food and Drug Administration will review and evaluate all data and information bearing on the safety of olestra received by the agency after the effective date of this regulation, and will present such data, information, and evaluation to the agency's Food Advisory Committee within 30 months of the effective date of this regulation. The purpose of such presentation will be to receive advice from the Committee on whether there continues to be reasonable certainty that use of olestra in compliance with this regulation is not harmful. The agency will hold such additional Food Advisory Committee meetings on olestra as the agency determines, in its discretion, to be necessary. Based upon the results of this entire process, the FDA will initiate any appropriate regulatory proceedings.

[61 FR 3171, Jan. 30, 1996; 61 FR 11546, Mar. 21, 1996]

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC_2H_5) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as follows:

(1) As a binder and filler in dry vitamin preparations.

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.

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§ 172.870 Hydroxypropyl cellulose.

The food additive hydroxypropyl cellulose may be safely used in food, except standardized foods that do not provide for such use, in accordance with the following prescribed conditions:

(a) The additive consists of one of the following:

(1) A cellulose ether containing propylene glycol groups attached by an ether linkage which contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 145 centipoises for 10 percent by weight aqueous solution at 25 °C.

(2) A cellulose ether containing propylene glycol groups attached by an ether linkage having a hydroxypropoxy ($\text{OC}_3\text{H}_6\text{OH}$) content of 5 to 16 percent weight in weight (w/w) on an anhydrous basis, i.e., 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit. The common name for this form of the additive is low substituted hydroxypropyl cellulose.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(2) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is used in accordance with good manufacturing practice.

[46 FR 50065, Oct. 9, 1981]

§ 172.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula $[\text{C}_6\text{H}_{(10-x-y)}\text{O}_5(\text{CH}_3)_x(\text{C}_2\text{H}_5)_y]_n$, where x is the number of methyl groups and y is the number of ethyl groups. The average value

of x is 0.3 and the average value of y is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH_3 , and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC_2H_5 , both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20 °C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004-65-3) may be safely used in food, except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

(b) The additive is used or intended for use as follows:

Use and Limitations

Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.

Vitamin and mineral tablets—As a component of protective coatings.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the "Journal of the Association of Official Analytical Chemists," Volume 45, page 66 (1962), which is incorporated by reference, after correction of the ultraviolet absorbance for any absorbance due to added antioxidants. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows: